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Research Article

The Impact of Daisies Capsule on Hot Flashes in Postmenopausal Women

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Abstract

Introduction and Purpose: Menopause is an important issue in women's life that brings about a transition to a new biological status and the gradual loss of fertility. Menopause is the transition from fertility to infertility, and it is regarded as an indication of old age and a predictor for diseases and health problems, and women's only experience is that their menstrual periods stop. Women experience numerous problems including hot flashes in menopausal period. Given the midwife's duties for promoting the health status of menopausal women, the present research aims at studying the effect of oral chamomile capsule on hot flashes in menopausal women.

Method: The present study is a triple blind clinical trial conducted on 82 menopausal and premenopausal women experiencing hot flashes. The samples were randomly divided into two 41-participant groups. One of the intervention groups received two capsules a day, each of which contains 250 milligrams of chamomile extract. The other group received two capsules containing starch for 8 weeks. After the intervention, the hot flashes mean scores were determined using the intensity recording form and the duration and number of hot flashes. Data analyses were conducted using a variety of tests including ANOVA, Kruskal-Wallis, Chi-square, Mann Whitney, Wilcoxon, and Friedman.

Findings: The findings obtained in the present study indicated that the hot flashes mean scores of the placebo group were 4.42 ± 1.93, 4.4 ± 3.026, and 0.62 ± 3.06, and the mean scores of the chamomile group were 3.63 ± 3.96, 2.25 ± 2.65, and 4.02 ± 4.22; the difference of the scores was significant in the chamomile group. In the end, 74 individuals participated in the intervention.

After 4 and 8 weeks of intervention, improvement was observed in the number, intensity, and duration of hot flashes in both groups that is statistically significant. However, the effect was more observable in the intervention group than the placebo group ($p < 0.0001$).

Conclusion: The findings of the present study indicate that taking at least one capsule of chamomile a month can be effective in treating the hot flashes of menopausal women. Thus, taking chamomile capsule, as a herbal supplement, is recommended for these women.

Keywords: *Menopause; Chamomile; Hot Flashes*

Introduction

Menopause is an important issue in women's life that brings about the transition to new biological status and the gradual loss of fertility. Menopause is the transition from fertility to infertility, and it is considered as an indication of old age as well as a predictor of diseases

and health problems. Women's only experience is that their menstrual periods stop [1]. The increasing menopausal age in different countries is associated with reasons beyond the increasing life expectancy; it has to do with nutrition and public health status [2].

The menopausal age ranges from 46.01 to 52.4 in different cities of Iran; the mean is 48.18 (Rajaei Fard, Beigi, and Salehi, 2011). Hot flashes account for the main symptom of menopause and it is behind most of the complaints made by women [3].

Hot flashes are sudden feelings of feverish heat that starts from the back of the head or neck. It is then spread all over the body and it is accompanied by intense heat. Hot flashes are preceded by the feeling of heartbeat or pressure inside the head. Hot flashes are likely to be accompanied by perspiration, anxiety, inflammability, and panic. Hot flashes are followed by cold and shivering. The duration of hot flashes ranges from some seconds to some minutes. In average, hot flashes last for 4 minutes. However, they are likely to last for 10 minutes; each time, five or ten times, and 30 times a day. This status is even more intense at night, or it occurs more frequently waking the person up [4]. Menopause is accompanied by nightly perspiration, sleeping disorder, inflammability, and disorders in memory and concentration.

The prevalence of hot flashes in menopausal women has been reported up to 70 percent. It has been reported that hot flashes are more intense and more frequent during the night. The prevalence of hot flashes has been reported to be 70 - 85 percent in Europe and 49 - 56 percent in Iran. However, in countries rich in vegetarian foods, such as China and Japan, it has been reported to be 8 - 17 percent [4]. For most women, hot flashes stop automatically without receiving any treatment within a few years. In one-third of the women, the symptoms of hot flashes can last more than 5 years. In 20 percent of the women, the symptoms can be constantly seen for up to 15 years [5].

Europe, and 49 - 56 percent in Iran. However, in countries rich in vegetarian foods, such as China and Japan, it has been reported to be 8 - 17 percent. For most women, hot flashes stop automatically without receiving any treatment within a few years. In one-third of the women, the symptoms of hot flashes can last more than 5 years. In 20 percent of the women, the symptoms can be constantly seen for up to 15 years [5]. The prevalence of hot flashes has been reported to be 70 - 85 percent in The prevalence of hot flashes in menopausal women has been reported to be up to 70 percent. They have been reported to be more intense and even more frequent at night bringing about sleeping disorders accompanied by intense perspiration and shivering [6]. Thus, findings solutions to treat hot flashes, being one of the most common problems of menopause, can play an important role in maintaining the menopausal women's mental and physical health and perpetuating a peaceful life for them [7].

Plants such as valerian, Black Cohosh, Chamomile, hyper cum perforatum, Liquorice, Fennel, soybean, red clover with phytoestrogen quality have been recommended for treating menopause [8]. Chamomile is of the chicory family that is one of the oldest plants used in medicine, and it is known as Matricaria Chamomilla all over the world. Its medical usage is internationally known and it is one of the most commonly used medicinal plants [9]. In most of the Iranian cities, it is planted largely. It has benefits such as reduced fever and perspiration, reducing headaches and migraine pains, arthritis, relieving menstrual pains, relieving menopausal complications, lowering blood pressure, relieving vertebral column pains, disinfectant uses, gastric anti-inflammatory effect, anti-itch effects, appetizing and carminative effects, antiemetic effects, restiveness, and herpes, preventing osteoporosis, and reducing rheumatism pains. Chamomile is also used locally for treating mastitis and hemorrhoid. In Europe and western Asia, chamomile tea has been used for feeling relief and improving one's sleep for than one hundred years. Chamomile has been often used as a mild sedative and sleep inductor, Chamomile helps nerve relaxation. It can also lead to reduced anxiety, nightmare, insomnia, and other sleeping disorders [10]. In Britain, chamomile is used as an aspirin [11]. Given article 2 of the national law for midwife's job description, one of the most important duties of the midwives is promoting women's health in menopausal period. According to article 6 of the aforementioned law, timely introduction and prescription of herbal supplements is one of duties of the midwives. Given the dangerous complications and side effects arising from the hormone replacement therapy, adopting natural, complication-free, and cheap therapies such as medicinal plants have been widely welcomed by the public. Thus, given the cost-effectiveness and availability of chamomile, the present study aims at studying its effect on the hot flashes of menopausal women, so that a step is taken towards the goals of developing and promoting women's health in both family and society.

Materials and Methods

The present study is a random triple blind clinical trial conducted on two groups. The statistical population of the present study includes 82 45-to-60-year-old menopausal women referring to the menopausal clinic of the comprehensive women's health care hospital; they were reported to complain about hot flashes. The inclusion criteria of the present study include :being 45 to 60 years old; suffering from hot flashes for at least 3 months; complaining about hot flashes for at least 3 times a day; not receiving hormone therapy in the last 3 months; not receiving therapy through taking drugs for sedating the menopausal symptoms; not receiving therapy through taking phytoestrogens such as soybeans and, not suffering from heart diseases, blood pressure, diabetes, mental disorders, thyroid disorders, liver diseases, cancer, abnormal uterine bleeding; not taking anxiolytics ; not taking any medicinal plants; not taking anticoagulants; not taking any soporific drugs; and not smoking. The exclusion criteria are as follows: taking anxiolytics, soporific drugs, anticoagulants such as aspirin, warfarin, and heparin; taking phytoestrogens and non-hormonal drugs such as clonidine for sedating menopausal symptoms; receiving hormone-therapy during the study; having allergy to chamomile during the study; suffering from abnormal uterine bleeding or any other systemic diseases during the study; and lack of willingness to proceed the study. The data tool of the present study include a demographic form including the participant's age, last-menstrual-period age, level of education, employment status, marital status, number of deliveries, and number of children, and a questionnaire for studying the daily hot flashes recording form over the last month. The method for recording the hot flashes is that a symbol is recorded each time for the hot flashes when they happen (morning, noon, night). For determining the intensity of hot flashes, according to the recommendation made by Food and Drug Administration of the Islamic Republic of Iran, the hot flashes intensity was classified as free of symptoms, minor (feeling of heat without perspiration), average (feeling of heat and perspiration, without disturbing the daily activities), and intense (feeling of feverish heat and perspiration disturbing the daily activities); the scores given were 0, 1, 2, and 3 respectively. The number of hot flashes was recorded on a daily schedule and the mean will be obtained.

The hot flashes duration is more than 5 minutes, 3 - 5 minutes, 1 - 3 minutes, 30 - 60 seconds, and less than 30 seconds; the average is obtained though. The weekly average of each variable is measured separately through dividing its total (over a week) to the number of days of the same week in which the form is filled out. The findings are evaluated based on the average changes of the mean of each variable during the intervention in comparison with those obtained at the outset of the study (Baghdari., *et al*. 2009). The less the mean score, the less the duration, intensity, and number of hot flashes will be.

The hot flashes recording form has been previously used by the researchers outside the country. The academic credit of the form has been measured through evaluating it content validity. Having been translated, the form's face validity as well as content validity were confirmed by 12 faculty members of Mashhad University of Medical Sciences (Baghdari., *et al*. 2009). Moreover, the validity of the tool has been measured by evaluating its content validity in a study conducted by Sadeghi., *et al*. (2012) at the Nursing and Midwifery School of Tehran University of Medical Sciences as well as another study conducted by Nahidi., *et al*. (2008) at Shahid Beheshti University of Medical Sciences.

The reliability of this form was confirmed at Mashhad University of Medical Sciences in a pilot study applying test-retest method by obtaining r = 0.87 and r = 0.9 respectively (Baghdari., *et al*. 2009). Moreover, at Shahid Beheshti University of Medical Sciences, for measuring the validity and reliability of the tool, content validity and retest were used with the correlation coefficient of r = 0.96 [12-14].

Having delivered the letter of consent, the qualified women were randomly placed in one of either of two groups. The drugs were classified by a pharmacist into two groups; A and B. The route of administration was taught for both groups. The chamomile user group took chamomile capsule (250 milligram a day, in two divided dose), and the control group took two capsules containing 250 milligram of starch twice a day for 8 weeks. The capsules have been produced by the researchers at Tarbiat Modares University Research Center of Medicinal Plants. Both the researcher, the participants of the present study, and the data analysts were unaware of the kind of capsules used. Both capsules were the same shape produced with A and B codes by the consultant pharmacist and were given to the research participants.

For conducting the supervision need on the route of administrating the capsules, the researcher controlled the route of administration by calling the participants; in case of taking the wrong route in administrating the capsules or having any other exclusion criteria, the participant was then excluded from the study. The data was analyzed using SPSS 22.b as well as other tests such as independent t-test, chi-square, Mann Whitney, and Wilcoxon.

Findings

Of the 82 participants, 41 received chamomile capsules, and 41 received placebo capsules (containing starch). During the administration of the drugs, 4 women from the chamomile group (2 owing to diarrhea and 2 owing to gastrointestinal complications), and 4 women from the placebo group (2 owing to irregular taking of the drugs and 2owing to diarrhea) were excluded from the study. In the end, the analysis was conducted on 74 women. Table 1 indicates that both groups were similar with respect to age, last-menstrual-period age, average number of deliveries, and number of children, and number of abortions. With respect to their employment status, most of the participants were housewives (%83.8 in the test group, and %75.7 in the control group). 94.5 percent of the test group and 70.3 percent of the control group enjoyed average economic status. 100 percent of the test group and 91.9 percent of the control group were married. With respect to the educational level, most of the participants had finished middle school or secondary school (%35 in the test group). Wilcoxon test in tables 2 and 3 indicates that the intensity, duration, and number of hot flashes in the two groups differ significantly before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention ($p \leq 0.0001$).

Group	Placebo standard deviation ± mean	Chamomile standard deviation ± mean	P-value
Age	52.24 ± 4.41	52.73 ± 4.26	p = 0/082
Last-menstrual-period age	47.7 ± 47.38	47.38 ± 3.174	p = 0/062
Number of deliveries	0.065 ± 10.60	0.059 ± 0.0865	p = 0/062
Number of children	3.024 ± 1.83	3.27 ± 1.194	p = 0/077
Number of abortion	0.065 ± 1.06	0.059 ± 0.0865	p = 0/09

Table 1: *The Comparison of demographic information mean and standard deviation in chamomile group and placebo group.*

	Groups	SD ± Mean	SD ± Mean	SD ± Mean
Chamomile	Before	4.022 ± 4.22	6.30 ± 376	2.17 ± 0.038
	4 weeks after the intervention	3.36 ± 3.96	8.27 ± 5.28	1.37 ± 0.075
	8 weeks after the intervention	25.2 ± 2.65	6.730 ± 5	1.039 ± 0.0174
Placebo	Before	0.622 ± 3.06	7.84 ± 6.25	2.039 ± 0.0389
	4 weeks after the intervention	4.4± 3.026	4.76 ± 6.05	1.4 ± 0.055
	8 weeks after the intervention	4.42 ± 1.93	12.76 ± 5.26	1.1 ± 0.484
P value	Before	0.08	0.06	0.012
	4 weeks after the intervention	0.003	≤0.0001	≤ 0.0001
	8 weeks after the intervention	0.0001	≤ 0.0001	≤ 0.0001

Table 2: *The frequency distribution of intensity, duration, and number of hot flashes in three phases: before* the *intervention, 4 weeks after the intervention, and 8 weeks after the intervention.*

The findings of Kruskal–Wallis *statistical test indicates that the duration, intensity, and number of hot flashes in the two groups did not show a significant difference before the intervention, and the groups are similar in this regard. However, the groups showed a significant difference 4 weeks and 8 weeks after the intervention.*

Groups	Mean ± SD	Mean ± SD	Mean ± SD	Friedman
Chamomile	2.17 ± 0.038	2.2 ± 0.0625	5.22 ± 4.02	p ≤ 0.001
	371 ± 0.0756	811 ± 0.815	3.36 ± 3.96	p ≤ 0.001
	170 1.039 ± 0.704	10 0.961 ± 0.85	2.25 ± 2.65	p ≤ 0.001
Placebo	2.393 ± 0.319	324 ± 0.717	622 ± 3.06	1.0041
	2.012 ± 0.055	1.25 ± 0.086	40	1.37
	1.822 ± 0.484	0.96 ± 0.08	3.1 ± 3.026	1.17

Table 3: *The comparison of weekly mean and standard deviation of the duration, intensity, and number of hot flashes before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention in chamomile group and placebo group.*

The findings obtained from Friedman test and its post-hoc Wilcoxon test: The chamomile and placebo group did not show a significant difference with respect to the duration, intensity, and number of hot flashes before the intervention. However, the duration, intensity, and number of hot flashes showed a significant difference 4 weeks and 8 weeks after the intervention ($p < 0.0001$).

By comparing the mean difference and standard deviation of the two groups, Mann Whitney test seems to be effective in reducing the intensity, duration, and number of hot flashes before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention ($p = 0.0001$).

Discussion

One of the most important reasons behind hot flashes in the menopausal period is the reduced sexual hormones. Physical as well as mental changes related to the hormones bring about hot flashes in these ages. The study conducted by Yazdani., *et al*. (2004) aiming at studying the effect of chamomile on dysmenorrhea and premenstrual syndrome indicated that chamomile turned out to be effective for relieving abdominal and pelvic pain, fatigue and lethargy, and anger; it can help reduce these symptoms significantly [15]. In the study conducted by Kupfer., *et al*. (2003) aiming at studying the effect of chamomile and dong quai combination on the menopausal symptoms for 12 weeks, the findings indicated that there was a remarkable reaction in the intervention group in the first month of therapy for improving sleeping disorder and fatigue. Moreover, the placebo had no effect on the improvement of sleep. This is consistent with the findings of the present study about the effect of chamomile and the ineffectiveness of placebo [16]. The study conducted by Vahidi., *et al*. (2007) aiming to compare the chamomile extract and morphine showed that the analgesic effect of chamomile is similar to that of morphine. Flavonoid combinations are responsible for the spasmolytic effects. They are analgesic, and the essences, especially bisabolol and chamazulene, are responsible for the anti-inflammatory effects [17].

The study conducted by Jenabi., *et al*. (2009) aiming to study the effect of chamomile tea on primary dysmenorrhea indicated that chamomile tea brings about an improvement of the menstrual pain. The mechanism of chamomile has been proved to be effective for improving dysmenorrhea and premenstrual syndrome. It is owing to the extract and ethanol taken from the flowers of this plant; they have anti-inflammatory, anti-spasmolytic, sedative and anti-restive effects [18].

Concerning the effect of placebo, there are contradictory findings. In the study conducted by Kazemian (2006) aiming to study the effect of valerian on menopausal women's hot flashes, the placebo brought about a reduction of hot flashes from %36.8 to %15 ($p < 0.05$). Thus far, no other studies have been conducted to study the effect of chamomile on the hot flashes. However, other medicinal plants (having phytoestrogenic effects) have been used to treat hot flashes [18].

Kazemian's study (2006) aimed to study the effect of valerian on menopausal women's hot flashes. It was conducted on 48 women for 2 months. Valerian turned out to be effective in reducing the duration of hot flashes 2 months after the treatment ($p < 0.05$). Moreover, it turned out to be effective in reducing the number of hot flashes 1 month after the treatment ($p < 0.05$) [19].

The study conducted by Kazemian (2006) aimed to study the effect of passion flower on menopausal women's hot flashes; it was conducted on 54 menopausal women for 30 days and indicated a significant reduction in the intensity of hot flashes ($p < 0.05$) [20].

The study conducted by Taghizadeh., *et al*. (2005) aimed to study the effect of vitagnus on the early menopausal complications; it was conducted on 50 menopausal women for 3 months and indicated a significant reduction in the amount of menopausal complications and showed great improvement of hot flashes (%52.2). The findings of all these studies are consistent with those of the present study; chamomile has been proved to be effective on the number, duration, and intensity of the hot flashes [21].

Table 3 shows the comparison of intensity, duration, and number of hot flashes before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention in both groups. The findings of Kruskal-Wallis statistical test indicates that the duration, intensity, and number of hot flashes in the two groups did not show a significant difference before the intervention, and the groups are similar in this regard ($p = 0.6$). However, the groups showed a significant difference 4 weeks and 8 weeks after the intervention ($p \geq 0.001$).

Given the contradictory findings on taking this herbal supplement, more studies need to be conducted in this regard. The intervention with a larger sample size and a longer follow-up was not possible. Thus limited sample size and short follow-up are the limitations of the present study.

Conclusion

The findings of the present study indicated that chamomile capsules are effective in improving the menopausal women's hot flashes. Thus, the midwives and gynecologists are recommended using chamomile plant as a safe, cheap, and harmless remedy in treating menopausal women's hot flashes.

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